UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

KERRY LANGSTAFF and BRADSHAW LANGSTAFF, Individually, and on Behalf of KAITLYN SIERRA LANGSTAFF, a minor child,	§	
Plaintiffs,	§	CIVIL ACTION No.
v.	§	
MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a Division of MCNEIL-PPC, INC.; and JOHNSON & JOHNSON,	§	
Defendants.	§	

PLAINTIFFS' ORIGINAL COMPLAINT-DEMAND FOR JURY TRIAL

COME NOW Kerry Langstaff and Bradshaw Langstaff, Individually, and on Behalf of Kaitlyn Sierra Langstaff, a minor child, (hereinafter "plaintiffs"), and file Plaintiffs' Original Complaint against McNeil Consumer & Specialty Pharmaceuticals, a Division of McNeil-PPC, Inc., and Johnson & Johnson, (hereinafter "defendants"), and would show the following:

I.
PARTIES

Plaintiffs Kerry Langstaff and Bradshaw Langstaff, Individually, and on Behalf of Kaitlyn Sierra Langstaff, a minor child, are citizens and residents of Santa Clara County, California.

Defendant McNeil Consumer & Specialty Pharmaceuticals, a Division of McNeil-PPC, Inc., is a corporation organized under and by virtue of the laws of the state of New Jersey, with a principal place of business in Montgomery County, Pennsylvania. Service of process may be

obtained on them by serving their registered agent for service, CT Corp. System, 350 N. St. Paul Street, Dallas, Texas 75201.

Defendant Johnson & Johnson is a corporation organized under and by virtue of the laws of the state of New Jersey, with a principal place of business in Middlesex County, New Jersey. Service of process may be obtained on them by serving their registered agent for service, M. H. Ullmann, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-0000.

II.
JURISDICTION AND VENUE

Jurisdiction and venue are proper in the United States District Court, Northern District of California, San Jose Division, under 28 U.S.C. §1332, based on diversity of citizenship and the amount in controversy exceeding $75,000, because plaintiffs are residents of the State of California, and defendants are all residents of states other than California; and under 28 U.S.C. §1391(a)(2), because a substantial part of the events or omissions giving rise to this claim occurred in Santa Clara County, California. California courts have personal jurisdiction over defendants because defendants conduct or conducted at all relevant times business throughout California, including this District and Division.

Soecifically, defendant McNeil Consumer & Specialty Pharmaceuticals, a Division of McNeil-PPC, Inc., (hereinafter “McNeil”, or “the defendant McNeil”) is a corporation organized under and by virtue of the laws of the state of New Jersey, and has a principal place of business in Montgomery County, Pennsylvania, which is qualified to do business in California, and doing business in Santa Clara County, California. California courts have personal jurisdiction over McNeil because it conducts business throughout California, including this District and Division.

Defendant Johnson & Johnson (hereinafter “J & J”, or “the defendant J & J”) is a

corporation organized under and by virtue of the laws of the state of New Jersey, and has a principal place of business in Middlesex County, New Jersey, which is qualified to do business in California, and doing business in Santa Clara County, California. California courts have personal jurisdiction over Johnson & Johnson because it conducts business throughout California, including this District and Division.

III.
STATEMENT OF FACTS

Defendant McNeil is a wholly owned subsidiary of defendant J & J, and both were at all material times hereto in the business of designing, manufacturing and marketing an over-the-counter (OTC) nonsteroidal anti-inflammatory analgesic drug called Children's Motrin, generic name ibuprofen (hereinafter "the drug"). Defendant McNeil is primarily responsible for manufacturing and distributing the drug, under the direction and control of defendant J & J.

McNeil is in the business of designing, manufacturing, selling and distributing the drug OTC directly to consumers and users in California and throughout the United States through various retailers, including but not limited to grocery stores and pharmacies. Defendants intended that the product reach the user or consumer such as plaintiffs in the condition in which it was originally sold and distributed by them.

Further, defendants put this product into the stream of commerce without any altercation or modification of the product by any distributor or retailer. Additionally, at all material times defendants manufactured, distributed, and marketed the drug to be sold to consumers in California and throughout the United States.

On or about April 6, 2002, Kaitlyn Sierra Langstaff, an eight year-old female with no known drug allergies, was in a state of good health when she was given Children's Motrin for

fever and sore throat by her parents, Brad and Kerry Langstaff. The next day she broke out in a rash. She continued to take the drug every 4-6 hours when she sought care at Fresno's Children's Hospital where she was diagnosed with toxic epidermal necrolysis ("TEN"). Shortly thereafter she was admitted to the PICU. Because of her skin and mucosal involvement, she was intubated, and she was required to have operative debridements. On the third or fourth night in the PICU, a physician at the hospital recommended discontinuation of the drug.

From there, she was transferred to Children's Hospital Los Angeles, where she was cared for in their Pediatric Intensive Care Unit. She developed Acute Respiratory Distress Syndrome ("ARDS") and required a permanent tracheostomy to provide mechanical ventilatory support as a result of deteriorating respiratory function. She also had multiple bronchoscopies and laryngoscopies for lysis and palatal adhesions. In addition, she required blood pressure support with dopamine and epinephrine, as well as multiple blood transfusions. Further, she had Pseudomonas bacteremia and urinary tract infection, as well as Candida parapsilosis bacteremia.

On or about May 28, 2002, she was transferred from Children's Hospital Los Angeles to Lucile Salter Packard Children's Hospital at Stanford for further management and support where she was treated for two to three weeks. She was then transferred to Santa Clara Valley Medical Center where she was hospitalized for several months.

During her hospitalization, she was in excruciating pain caused by her skin sloughing off her body, comparable to second degree burns, but since they were not full thickness burns, all nerve endings were exposed, leaving her in terrible pain. Additionally, because of the loss of her skin and blood, she suffered secondary infections and massive bleeding, requiring multiple blood transfusions; all of which required her to be heavily sedated and restrained to her bed.

She also developed severe esophageal and vocal cord damage and could not talk until she was provided an electro-pharyngeal stimulator to effectuate speech. She also is fed a formula through a feeding tube every day. She has suffered extensive scarring to her corneas and is functionally blind, and now only able to read by Braille. She had palatal adhesions where her tongue stuck to her palate which had to be surgically separated. She has bronchiolitis obliterans and permanent lung damage. She also suffers from severe hypertension probably related to permanent kidney damage, requiring constant medication.

She has also developed severe depression and anxiety, and is wheelchair bound. She has suffered ear and hearing damage to both ears, especially the left ear, and continues to have ear tubes in place, and have her hearing monitored closely. Additionally, she will require multiple additional surgeries in the future, and permanent and possibly full-time medical and custodial care for her catastrophic injuries.

Plaintiffs had no knowledge of any unseen potential dangerous defect or condition in the drug at the time Kaitlyn used it, and certainly no knowledge that it could cause SJS/TEN. Nor did McNeil or J & J warn in any of the materials distributed with the drug, in the package insert, or on the drug box, or in any of its advertising designed to reach the consumer, that the drug could cause SJS/TEN, or a mucocutaneous lesion, or what to do if a rash or mucosal lesions developed. Plaintiffs used the drug in the manner intended and in accordance with instructions included with the drug by defendants for use as pharmacologic treatment for her fever. As a direct and proximate result of using the drug, plaintiff Kaitlyn Sierra Langstaff suffered serious, painful, and permanently disabling injuries.

IV.
CAUSE OF ACTION AGAINST ALL DEFENDANTS

A. Defective Design

Plaintiffs adopt all of the foregoing allegations in paragraphs III by reference, as if incorporated verbatim herein. Additionally, they allege that the drug was defectively designed by defendants McNeil and J & J so as to render it unreasonably dangerous to plaintiff and other persons similarly situated. In particular, it contained the chemical constituent propionic acid and other ingredients, rendering it more toxic than other non-propionic acid based NSAID drugs, and more dangerous to certain persons, particularly females and children, than other NSAIDS or fever-reducing products.

Additionally, defendants failed to adequately test the drug for over the counter use with children before presenting it to the FDA for such use, and before selling and distributing it to the general public; and/or failed to adequately and completely report the clinical trials data regarding the drug.

Additionally, a safer alternative design would have prevented or significantly reduced the risk of plaintiff's injuries, without substantially impairing the drug's utility. Furthermore, a safer alternative design was economically and technologically feasible at the time the drug left the control of defendants by the application of existing or reasonably achievable scientific knowledge. Finally, the drug's risk to children far outweighed its benefit, particularly considering that there were other drugs on the market, such as Tylenol, which were safer and equally as effective.

B. Marketing Defect

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference, as if incorporated verbatim herein. Additionally, they allege that the drug was also defective and

unreasonably dangerous because there was no warning, or alternatively, no adequate warning that consumption of this drug could result in SJS or TEN, or in any type of severe life-threatening skin reaction.

The warnings and instructions that accompanied the drug provided inadequate warnings to the consumer about the risk of SJS/TEN, the degree of the risk of SJS/TEN, and about other serious skin reactions associated with the use of the drug, or what to do in the event the patient suffered an adverse skin reaction to the drug. Specifically, there was no warning that if a rash or mucosal reaction developed, that the drug should be stopped immediately and medical care should be sought. Nor was there any warning that there was a greater risk of such skin reactions in females. These marketing defects were the producing cause of the plaintiff's permanent injuries and damages.

C. Breach of Express Warranty

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference, as if incorporated verbatim herein. Additionally, they allege that defendants made express warranties as to the drug's utility in treating fever and pain symptoms/conditions, without making clear the extreme danger associated with a toxic reaction to this drug. The express warranties described were part of the basis of the bargain between plaintiffs and defendants. The drug was not of the quality or condition expressly warranted by the defendants' affirmations, and defective in that the drug is inherently dangerous to children, particularly females, and therefore cannot be used in the manner intended without serious risk of physical injury to the user.

D. Breach of Implied Warranty

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference as if

incorporated verbatim herein. In addition, they allege that defendants impliedly warranted to the public generally and specifically to the plaintiffs that the drug was of merchantable quality and was safe and fit for the purpose intended when used under ordinary circumstances and in an ordinary manner. Defendants knew or had reason to know of the purposes for which plaintiffs purchased the drug; that plaintiffs were relying on defendants' skill and judgment to select and furnish a suitable drug; and that the drug in question were unfit for the purpose for which it was intended to be used.

E. Negligence

Plaintiffs adopt all of the foregoing allegations in paragraphs III and IV by reference as if incorporated verbatim herein. Additionally, they allege that defendants, particularly the defendant McNeil, had a duty to use reasonable care in labeling, packaging, marketing, selling, advertising, warning, and otherwise distributing the drug. However, McNeil placed the drug on the market without warning the user or consumer that consumption of this drug could result in SJS or TEN, or other severe skin reactions.

Additionally, they failed to warn plaintiffs to stop the drug immediately and seek medical attention if any skin rash or mucosal lesions developed, because of the danger that such symptoms could progress to SJS/TEN. These acts and omissions, taken by themselves or in combination, were negligence and were a proximate cause of the plaintiff's permanent injuries and damages.

Each and all of the foregoing acts or omissions on the part of defendants, acting separately and collectively, were a proximate cause of the injuries and damages sustained by the plaintiffs herein.

V.
DAMAGES

Plaintiffs seek damages from defendants, jointly and severally, for the injuries and damages caused by use of the product manufactured, marketed and sold by defendants in an amount in excess of the minimum jurisdictional limits of this Court. It is not possible for plaintiffs to plead the exact amount of these damages at this time, but they will be pleaded at a later time when they can be determined and as may be required by the rules.

Plaintiffs allege that the foregoing negligence and strict liability of defendants, acting separately and collectively, was a direct, proximate and/or producing cause of the damages suffered by plaintiffs herein.

As a direct and proximate/producing result of the negligence and strict liability of defendants as set out above, Plaintiff Kaitlyn Sierra Langstaff has suffered the following injuries and damages, among others, for which defendants are jointly and severally liable:

1. Plaintiff Kaitlyn Sierra Langstaff has suffered physical impairment in the past and, in reasonable probability, such impairment will continue into the future;

2. Plaintiff Kaitlyn Sierra Langstaff has incurred extensive past medical and rehabilitation expenses for treatment of her injuries, and will incur future reasonable and necessary expenses for such medical care and treatment;

3. Plaintiff Kaitlyn Sierra Langstaff has suffered severe physical pain and mental anguish caused by her injuries, treatment and rehabilitation, and, in all reasonable probability, will continue to suffer in this matter in the future;

4. Plaintiff Kaitlyn Sierra Langstaff has suffered physical disability, including loss of hearing, and disfigurement in the past, and will continue to suffer from this disability and disfigurement in the future;

5. Plaintiff Kaitlyn Sierra Langstaff has suffered permanent vocational impairment to her ability to perform any meaningful employment, rendering her totally and permanently disabled.

As a direct and proximate result of the negligence and strict liability of defendants as set out above, Plaintiffs Kerry Langstaff and Bradshaw Langstaff have suffered the following injuries and damages, among others, for which defendants are jointly and severally liable:

1. Past and future loss of consortium, companionship, and impairment to the parent-child relationship;

2. Medical, rehabilitative, and attendant care expenses to age 18 for Kaitlyn.

Plaintiffs request and hereby claim prejudgment and post-judgment interest as provided by law.

VI.
PUNITIVE DAMAGES

As a result of defendants' negligence and gross negligence in designing, manufacturing and placing into the stream of commerce a drug unsafe for the purpose intended; in failing to adequately warn the ultimate user and consumer of the inherent dangers in said drug; in failing to provide instructions for the safe use of said dangerous drug when defendants knew or should have known of the probable harm, injury or death the drug could cause to the user; and in deliberately failing to warn about the danger of this potentially disastrous toxic reaction; defendants should be held liable for gross negligence and intentional misconduct. Plaintiffs are therefore entitled to punitive and exemplary damages for the gross negligence of defendants. Plaintiffs also allege that each act of negligence by all of the defendants constituted individual and/or collective acts of gross negligence and/or malice against plaintiffs.

Specifically, plaintiffs adopt each of the allegations in paragraph III and IV by reference. These acts of negligence by all defendants involved an extreme degree of risk of harm to the plaintiffs. Specifically, there was a high degree of risk of harm from SJS/TEN from this drug

due to its constituents. Yet, they proceeded with conscious indifference to Kaitlyn Sierra Langstaff's safety and welfare; and/or alternatively, showed such actual conscious indifference to the rights, welfare, and safety of plaintiff to constitute gross negligence.

VII.
JURY DEMAND

Plaintiffs respectfully request a trial by jury and are tendering the required jury fee with this complaint.

WHEREFORE, PREMISES CONSIDERED, plaintiffs pray that defendants be cited to appear and answer herein, that upon final hearing of this cause, plaintiffs have judgment against defendants for actual, punitive, and all other damages as provided by law, together with interest as provided by law and costs of court, attorney's fees, and for such other and further relief, general and special, to which plaintiffs may be entitled, either at law or in equity.

Dated this ____ day of March, 2003.

Respectfully submitted,

MARY ALEXANDER & ASSOCIATES, P.C.
44 Montgomery Street, Suite 1303
San Francisco, California 94104-4612
Phone: (415) 433-4440
Fax: (415) 433-5440

By: _____
MARY E. ALEXANDER
State Bar No. 104173

LAW OFFICES OF JAMES C. BARBER
4310 Gaston Avenue
Dallas, Texas 75246
Phone: (214) 821-8840
Fax: (214) 821-3834

By: _____
JAMES C. BARBER
State Bar No. 01706000
JASON S. MARINA
State Bar No. 24011738

SPECTER, SPECTER, EVANS, & MANOGUE
Koppers Building, 26th Floor
436 7th Avenue
Pittsburgh, PA 15219-1818
Phone: (412) 642-2300
Fax: (412) 642-2309

By: _____
HOWARD A. SPECTER
State Bar No. 10986
JOHN EVANS
State Bar No. 49351

ATTORNEYS FOR PLAINTIFFS